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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/305,984 05/05/99 NOVAK

R 1340-1-016-N

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HM12/1109

EXAMINER

LEE, L

ART UNIT

PAPER NUMBER

1645

4

DATE MAILED:

11/09/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/305,984

Applicant(s)

Novak et al

Examiner

Li Lee

Group Art Unit

1645



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-67 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-67 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### **DETAILED ACTION**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

See the attached Raw Sequence Listing Error Report and note that Applicant's disclosure of amino acid sequences which are more than 4 amino acids in length in the specification and in the claims must comply with the sequence rules.

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, drawn to an isolated nucleic acid, classified in class 536, subclass 32.1.
  - II. Claims 11-20 and 24, drawn to a peptide, classified in class 530, subclass 350.
  - III. Claims 21-23, drawn to an antibody and the cell line producing the antibody, classified in class 530, subclass 387.1.
  - IV. Claims 25-28, drawn to a method of identifying a peptide locating an open reading frame in a gene cluster, classified in class 435, subclass 6.

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- V. Claims 29-33, drawn to a method of identifying a peptide locating an open reading frame is within one kilo base of a second open reading frame, classified in class 435, subclass 6.
- VI. Claim 34-39, drawn to a method of identifying an agent contacting the agent with a cell having defective His-Asp phosphorelay pathway, classified in class 435, subclass 7.1.
- VII. Claims 40-43, drawn to a method of identifying an agent contacting the agent with a cell having defective ABC transporter, classified in class 435, subclass 7.1.
- VIII. Claims 44-51, drawn to a cell having defective His-Asp phosphorelay pathway, classified in class 435, subclass 325.
- IX. Claims 52-58, drawn to a cell having defective ABC transporter, classified in class 435, subclass 325
- X. Claims 59-61, drawn to a method of identifying a pneumococcal cell containing a mutant histidine kinase gene comparing the PCR product with SEQ ID NO:14, classified in class 435, subclass 6.
- XI. Claims 62-64, drawn to a method of identifying a pneumococcal cell containing a mutant response regulator gene comparing the PCR product with SEQ ID NO:16, classified in class 435, subclass 6.

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XII. Claims 65-67, drawn to a method of identifying a pneumococcal cell containing a mutant gene for the ABC transporter comparing the PCR product with SEQ ID NOs:18, 20, and 22, classified in class 435, subclass 6.

2. The Groups I, II, III, VIII and IX are related as products. The claims of Group I are drawn to isolated polynucleotide, those of Group II are drawn to a polypeptide, that of Group III to antibody, and that of Group VIII are drawn to a cell having defective His-Asp phosphorelay pathway, Group IX to a cell having defective ABC transporter. The inventions can be shown to be distinct because they are made by different methods (e.g., in vitro chemical synthesis, recombinant production, injection of an animal with the protein) and because they are physically (e.g., amino acids versus nucleic acid or a cell) and functionally (e.g., mediate biological activity, encode proteins, mediate an immune response) distinct chemical entities.

Inventions IV, V, VI, VII, X, XI, and XII are drawn to independent and distinct methods which differ in the method objectives, method steps, in the reagents used, and have different final outcomes.

Inventions I / II and IV-VII, X-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups I and II as claimed can

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be used in a materially different process, such as making recombinant protein or in vitro purifying antibodies.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as shown by the different classification, and absent restriction would place an undue search and examination burden on the examiner, therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

3. The time period for response for both the Election /Restriction and the Sequence Requirements is hereby set to run concurrently. Failure to respond to both the Election/Restriction and the Sequence Requirements will be held non-responsive.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice

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published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee, M.D., Ph.D. whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Li Lee, M.D., Ph.D.  
November 1, 1999



ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600